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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,946	03/24/2000	Frank R. Ruderman	MBHB00-203	1964

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EXAMINER	
BLECK, CAROLYN M	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 01/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/534,946	RUDERMAN ET AL.	
	Examiner	Art Unit	
	Carolyn M Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Recent Statutory Changes to 35 U.S.C. § 102(e)

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.**

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.**

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at www.uspto.gov or call the Office of Patent Legal Administration at (703) 305-1622.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 5 November 2002. Claims 1-20 have been canceled. Claims 21-43 are newly added.

Specification

2. The objection of the abstract is hereby withdrawn due to the amendment filed 5 November 2002.

3. The use of the trademarks has been noted in this application. Some examples are Microsoft® and NT 4.0 Option Pack ™ (pg. 6 lines 1-2), Microsoft ® WebTV ™ (pg. 15 lines 18-19), and OpenTV ® (pg. 16 line 11). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is requested the Applicant use proper notation for trademarks.

4. The amendment filed 5 November 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added recitation of percentage distribution of LDL and HDL subclass particles data "derived from laboratory tests wherein the data is included," a physician dynamically selects parameters for treatment solutions "based on patient test results trends," and a diagnostic engine analyzes test results, patient data, diagnostic information and "provides a baseline determination for ongoing therapy monitoring" within claims 21, 29, and 34 appears to constitute new matter. In particular, Applicant does not point to, nor was the Examiner able to find, any support for data derived from laboratory tests, selecting parameters for treatment solutions based on patient test results trends, and providing a baseline determination for ongoing therapy monitoring within the specification as originally filed. As such, Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office action.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The specification is objected to under 35 U.S.C. 112, first paragraph, because the specification, as originally filed, does not provide support for the invention as is now claimed for the reasons given above in section 4.

Claim Objections

7. Claim 21 is objected to because of the following informalities: claim 21, line 4, "included." is grammatically incorrect. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 22, line 1, "The cardiovascular healthcare management system of claim 1" lacks proper antecedent basis as claim 22 depends on claim 1 which has been cancelled. For purposes of applying prior art, "The cardiovascular healthcare management system" of claim 22 is assumed to be dependent on claim 21.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 21, 29, and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and for the reasons set forth in the objection to the specification above.

Independent claim 21 recites limitations that are new matter, as discussed above. Dependent claims 29 and 34 recite limitations that are new matter, as discussed above.

Claims 22-28 and 30-33 incorporate the deficiencies of independent claim 21, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

NOTE: The following rejections assume that the subject matter added in the 5 November 2002 amendment are NOT new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter objections and rejections made in sections 4-6 and 10-11 above in the next communication sent in response to the present Office Action.

13. Claims 21-22, 24-28, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580) in view of the Applicant's admission in the background of the art of the present application (09/534,946).

(A) As per claim 21, Levin discloses a system for managing coronary disease data (reads on "managing cardiovascular healthcare information") (col. 1 lines 9-18, col. 2 lines 39-45 and 50-57, and col. 11 lines 12-15) comprising:

(a) a centralized data management center for maintaining a record of data received by and transmitted from relational databases relating to coronary disease data, wherein the processing means at the centralized data management center provide for analyzing patient test results (reads on "laboratory tests") using a coronary wellness master algorithm and artificial intelligence, such as ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (reads on "diagnostic engine") (Fig. 3 and 25A, col. 5 lines 1-36, col. 6 lines 16-28, col. 7 lines 55-63, col. 7 line 64 to col. 8 line 7, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10), wherein the processing means runs a lipid classification algorithm by inputting patient's LDL and HDL cholesterol values and checking the patient values against the upper limit for normal LDL and HDL cholesterol values, wherein the normal values are stored in the databases at the centralized data management center (Fig. 1-2, 4, and 11-15, Abstract lines 11-14, col. 5 lines 25-37, col. 8 line 21 to col. 9 line 40, col. 10 lines 56-57, and col. 11 lines 5-10);

(b) a monitor displaying a menu (reads on "data entry interface") for entering all known and required information, including patient information such as name, birth date, sex, height, and weight, and test results, such ECG information, and storing the information and test results at the centralized data management center databases (Abstract lines 11-14, Fig. 1-2, col. 4 line 53 to col. 5 line 36, col. 10 lines 50-57, and col. 11 lines 5-10); and

(c) processing means at the centralized data management center for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, such as ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient (reads on "diagnostic engine") (col. 7 lines 55-63, col. 8 line 21 to col. 39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10), wherein the algorithm correlates test results with possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15).

In addition, Levin includes within Figures 11-15 measuring HDL and LDL levels using the units of mg/DL and then classifying the patient into an appropriate class, either an elevated class or optimal class based on the HDL and LDL levels (col. 8 lines 21-47). It is noted that HDL and LDL levels are sub classes of a patient's total cholesterol (Fig. 11-15 and col. 8 lines 21-47). Levin fails to expressly disclose a percentage distribution of LDL and HDL subclass particles data. However, as per the Applicant's background of the art (see page 1 lines 15-24 of application 09/534,946), it

is noted that "the art describes cardiovascular risk factors such as age, smoking, weight, family history, blood pressure, lipid profiles including low density lipoprotein (LDL) and high density lipoprotein (HDL) and subclasses (fractions) of LDL and HDL, and methods for measuring these factors and relating them to treatment are known (emphasis added)." Furthermore, it is respectfully submitted that using a percentage distribution of data is a data analysis technique typically used for displaying data in graphical form, and the skilled artisan would have found it an obvious modification to include a percentage distribution of the LDL and HDL subclass particles data within the system taught collectively by Levin and Applicant's background of the art with the motivation of reducing the time for a physician to make a diagnosis and determine a treatment by providing a graphical means for efficiently and easily presenting patient data (Levin; col. 10 lines 16-38).

(B) As per claim 22, Levin discloses a monitor displaying a menu (reads on "physician data access interface") for providing a physician, such as a cardiologist, with the ability to access, display, review, and transfer information stored at the centralized data management center (col. 2 lines 1-15, col. 5 lines 49-67, and col. 11 lines 1-10).

(C) As per claim 24, Levin discloses a storage means that stores information related to coronary illness risk factors which have been established based on empirical data, wherein the information allows physicians to determine the effectiveness of diagnoses and treatments as the information is gathered over time and as the pool of treated

patients increases (Abstract lines 11-14, col. 6 line 3-15, and col. 10 lines 3-15). It is respectfully submitted that the storage means disclosed by Levin is a form of a knowledge base as the data collected in the database is a collection of knowledge of specialists such as cardiologists, and the data collected will be used to effectively identify patients at significant risk of sudden death and to quantify the success of various treatments both for the patient pool and fro particular patients (col. 6 line 3-15).

(D) As per claims 25-27 and 32-34, Levin discloses processing means at the centralized data management center for analyzing patient test results using a coronary wellness master algorithm and artificial intelligence, wherein patient test results include ECG information, lipid data, including total cholesterol, LDL cholesterol, and HDL cholesterol, and blood pressure of a patient, and wherein the test results determine base numbers for a patient (reads on "diagnostic engine" and "baseline determination for ongoing therapy monitoring") (Fig. 3, col. 5 lines 25-36, col. 6 lines 16-28, col. 7 lines 55-63, col. 7 line 64 to col. 8 line 7, col. 8 line 21 to col. 39, col. 9 lines 18-39, col. 10 lines 3-15, col. 10 lines 3-15 and lines 50-55, and col. 12 line 46 to col. 14 line 10) wherein:

(a) the algorithms correlate test results with possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy, diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15);

(b) the algorithms correlate test results with possible or recommended diagnoses, such as such as whether the levels of total cholesterol, LDL cholesterol, and HDL cholesterol are acceptable or not, and the diagnosis classification for blood pressure of a patient, wherein the classification includes normal, high-normal, mild hypertension, moderate hypertension, severe hypertension, and very severe hypertension (col. 8 line 21 to col. 9 line 39, col. 10 lines 3-15, and col. 11 line 10-15); and

(c) the algorithms correlate diagnosis information with possible or recommended treatments (Fig. 25A-B, col. 5 lines 16-37, col. 6 line 16 to col. 7 line 47, col. 8 line 21 to col. 9 line 39, and col. 10 lines 3-15).

(E) As per claim 28, Levin discloses the algorithms correlating test results with possible treatment recommendations with regard to antischemic therapy, hypolipidemic therapy, antihypertensive therapy, antithrombotic therapy (reads on "personalized drugs"), diabetes, smoking cessation, body weight, and exercise (Fig. 25A-B and col. 10 lines 3-15).

14. Claims 23 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (5,724,580) and the Applicant's admission in the background of the art of the present application (09/534,946) as applied to claim 21, and further in view of Surwit et al. (6,024,699).

(A) As per claim 23, the relevant teachings of Levin and the Applicant's admission in the background of the art of the present application (09/534,946), and the motivation for their combination is as discussed in the rejections above, and incorporated herein.

Levin and the Applicant's background of the art fail to expressly disclose a communication system allowing the physician to communicate cardiovascular healthcare management information to a patient. However, Levin includes communicating coronary illness information to and from a physician, such as a cardiologist, via communication network (Fig. 1-3 and 25A-25B, col. 2 line 62 to col. 3 line 10, col. 4 lines 31-55, col. 7 lines 33-47, and col. 7 line 64 to col. 8 line 7).

Surwit discloses a system for monitoring, diagnosing, prioritizing, and treating chronic medical conditions of a plurality of remotely located patients, wherein treatment information is provided to a patient via a computer network (Fig. 1 and 3, col. 2 lines 38-55, col. 3 lines 24-38, col. 6 line 27 to col. 7 line 13, col. 9 lines 24-58, col. 18 line 45 to col. 19 line 40).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned component of Surwit within the system taught collectively by Levin and Applicant's background of the art with the motivation of quickly and easily monitoring patients and automatically identifying a patient with a medical condition, quickly preparing and revising medicine dosages for a patient and then efficiently communicating revised dosage information to a patient (Surwit; col. 2 lines 25-35), and reducing the costs of medical treatment by providing a fast, effective technique for providing comprehensive management of coronary patients

based on risk factors including up to date diagnoses and treatment information (Levin; col. 2 lines 16-49).

(B) As per claim 29, the relevant teachings of Levin and the Applicant's admission in the background of the art of the present application (09/534,946), and the motivation for their combination is as discussed in the rejections above, and incorporated herein.

Levin fails to expressly disclose dynamically selecting parameters for treatment solutions based on patient test results trends. Surwit discloses allowing a case manager, including a physician, to select parameters from patient test results to view and compare over a period of time (Fig. 8-9, col. 17 line 40 to col. 18 line 30). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Surwit within the system taught collectively by Levin and Applicant's background of the art with the motivation of quickly and easily monitoring patients and automatically identifying a patient with a medical condition, quickly preparing and revising medicine dosages for a patient and then efficiently communicating revise dosage information to a patient (Surwit; col. 2 lines 25-35), and reducing the costs of medical treatment by providing a fast, effective technique for providing comprehensive management of coronary patients based on risk factors including up to date diagnoses and treatment information (Levin; col. 2 lines 16-49).

(C) As per claim 30, Surwit discloses transmitting physiologic or biologic data (e.g. body temperature and urine ketones), behavioral data (e.g. assessments related to diet,

exercise, stress, the presence of illness) and patient medication intake data (all data reads on "compliance information") from a patient (col. 2 line 25 to col. 3 line 55 and col. 7 lines 40-63), wherein the data is stored in a database for review by a case worker such as a physician (col. 7 lines 40-63, col. 10 line 24 to col. 11 line 32, col. 13 lines 40-62, and col. 18 line 45 to col. 19 line 12). The motivation for combining Surwit into Levin and the Applicant's background of the art is given above in claim 23, and incorporated herein.

(D) As per claim 31, Surwit discloses accessing chronic disease treatment information by a patient via a computer network through a menu driven display (reads on "patient access interface") (Fig. 1 and 3, col. 2 lines 38-55, col. 3 lines 24-38, col. 6 line 27 to col. 7 line 13, col. 7 line 40 to col. 9 line 22, col. 9 lines 24-58, col. 18 line 45 to col. 19 line 40). The motivation for combining Surwit into Levin and the Applicant's background of the art is given above in claim 29, and incorporated herein.

Response to Arguments

15. Applicant's arguments with respect to claims 21-34 have been considered but are moot in view of the new ground(s) of rejection.

16. Applicant's arguments filed 5 November 2002 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 5 November 2002.

(A) At pages 3-5 of the response filed 5 November 2002, Applicant argues that the newly added features in the 5 November 2002 amendment are not taught or suggested by the applied references, namely the percentage distribution of LDL and HDL subclass particle data.

In response, all of the limitation which Applicant disputes as missing in the applied references, include the features newly added in the 5 November 2002 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Levin, the Applicant's background of the art, and/or Surwit, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (see paper number 7), and incorporated herein.

Furthermore, the Examiner notes that Levin and the Applicant's background of the art were never applied as a reference under 35 U.S.C. 102 against the features recited in newly added claim 21. As such, the Examiner respectfully submits that the issue at hand is not whether the applied prior art specifically teaches the use of the percentage distribution of LDL and HDL subclass particle data as recited in claim 21, but rather, whether or not the prior art, when taken in combination with the knowledge of average skill in the art, would put the artisan in possession of these features. In the "Background of the Art" section of the present application, Applicant admits that "the art describes cardiovascular risk factors such as age, smoking, weight, family history, blood

pressure, lipid profiles including low density lipoprotein (LDL) and high density lipoprotein (HDL) and subclasses (fractions) of LDL and HDL, and methods for measuring these factors and relating them to treatment are known (emphasis added)." As such, using subclasses (fractions) of LDL and HDL data to assess cardiovascular risk was well established in the art prior to Applicant's invention. As per the percentage distribution of the data, the Examiner respectfully submits that Applicant is not the first to develop the concept of creating a percentage distribution of data. Insofar as claim 21 does not provide the details of the components of LDL and HDL subclass particle data, it is respectfully submitted that the disclosure by Levin is commensurate with the breadth of claim 21, and is sufficient to address the features as claimed, when considered collectively with the teachings of the prior art admitted by Applicant in "Background of the Art" section of the present application, and the knowledge of average skill in the art.

Further, assuming *arguendo* the Applicant is correct in his assertion that the system taught collectively by Levin and the Applicant's background of the art are different from that recited in claim 21, Applicant does not point to any specific language within claim 21 that positively and definitely distinguishes Applicant's percentage distribution of LDL and HDL subclass particle data from the prior art teachings of Levin and the Applicant's "Background of the Art" of the present application, and as discussed above. As such, the skilled artisan would readily recognize that the use of a percentage distribution of LDL and HDL subclass particle data were well known considerations for assessing cardiovascular risk in the prior art, and the courts have held that even if a

patent does not specifically disclose a particular element, said element being within the knowledge of a skilled artisan, the patent taken in combination with that knowledge, would put the artisan in possession of the claimed invention. *In re Graves,* 36 USPQ 2d 1697.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a medical wellness parameters management system, apparatus, and method (6,454,705), a tele-evaluation system for medicine (6,454,709), an automated diagnostic system and method (6,468,210), a digital disease management system (6,470,320), and a method and system for healthcare treatment planning and assessment (6,484,144).

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

20. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 305-7687 [Official communications; including After Final communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
January 6, 2003

DINH X. NGUYEN
PRIMARY EXAMINER